



Exciton Technologies Inc.  
exsalt™ Wound Dressing

K 100580

Premarket Notification 510(k)

## 510(k) Summary for exsalt™ Wound Dressing

OCT 12 2010

### 1. Trade (Proprietary) Name

exsalt™ Wound Dressing

### 2. Common Name

Wound or Burn Dressing

### 3. Contact Information

Contact : Mr. Rod Precht  
President and COO  
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Canada

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Date of 510(k) Summary Preparation: 17 September 2010

### 4. Device Classification & Panel

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

### 5. Predicate Device(s)

exsalt™ SD7 Wound Dressing (K083870)  
CURAD Silver Bandage (K032463)  
Silverlon Silver Strips™ Adhesive Strips (K023609)

### 6. Device Description

The exsalt™ Wound Dressing consists of 2 outer layers of HDPE with an inner layer of absorbent polyester, all coated with silver. Exciton Technologies Inc. has developed exsalt™ technology; a proprietary chemical process, which deposits oxidized silver species onto the non-woven

polyester coated with Delnet® HDPE mesh layers on both sides (STRATEX®). Silver in the exsalt™ SD7 Wound Dressing inhibits microbial growth in the dressing. The exsalt™ Wound Dressing has been shown to be effective *in vitro* against *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*.

## **7. Intended Use**

The exsalt™ Wound Dressing is indicated for first aid to help minor cuts, scrapes, abrasion, lacerations and scalds. The device is intended to be used over-the-counter. The exsalt™ Wound Dressing provides a barrier with silver as a preservative to inhibit microbial growth in the dressing. The exsalt™ Wound Dressing has shown to be effective *in vitro* against *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*.

## **8. Summary of Substantial Equivalence**

The labeled indications and directions for use of the exsalt™ Wound Dressing are equivalent to those of the predicate devices, CURAD® Silver Bandage and Silverlon Silver Strips™ Adhesive Strips. The device design, materials, and manufacturing methods are the same as exsalt™ SD7 Wound Dressing submission (K083870) and therefore does not raise any new issues concerning safety or effectiveness.

### **a) Summary of Technological Characteristics**

The exsalt™ Wound Dressing consists of 2 outer layers of HDPE with an inner layer of absorbent polyester which are all silver-coated. The skin-contacting materials in both the exsalt™ Wound Dressing and the predicate are the same. exsalt™ Wound Dressing was found to be safe in Biocompatibility Tests, including tests for irritation, sensitization, and cytotoxicity.

Silver is deposited on the exsalt™ Wound Dressing using an aqueous chemistry approach. The process produces oxidized silver species that are applied to the substrate. The application of silver to the dressing does not affect the efficacy or safety of the device as demonstrated by the results of the bactericidal and antimicrobial efficacy testing, and biocompatibility testing. The exsalt™ Wound Dressing and the predicate are sterilized by gamma irradiation. There were no changes in the exsalt™ Wound Dressing in terms of technological characteristics as compared to the predicate device exsalt™ SD7 Wound Dressing (K083870).

## **b) Summary of Performance Data**

The following performance tests were conducted on the exsalt™ Wound Dressing:

- Absorptive Capacity
- Moisture Content
- Drop Penetration
- Adhesion
- Abrasion
- Silver Content
- Anti-microbial (bacterial) Effectiveness
- Bactericidal Effectiveness
- Biocompatibility
- Biological Reactivity

Absorptive capacity, moisture content, adhesion, and abrasion characteristics were found to be substantially equivalent to the predicate.

The exsalt™ Wound Dressing showed no new safety concerns relative to biocompatibility. It was shown to be non-toxic, non-irritant, and does not elicit a sensitization response.

The exsalt™ Wound Dressing has been shown to be effective *in vitro* against *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Enterococcus faecalis*.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Exciton Technologies, Inc.  
% Ms. Melanie Ussyk, ASQ CQA  
Manager, Quality Assurance  
Suite 4000-10230 Jasper Avenue  
Edmonton, Alberta T5J 4P6  
Canada

OCT 12 2010

Re: K100580  
Trade/Device Name: exsalt™ Wound Dressing  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: September 30, 2010  
Received: October 1, 2010

Dear Ms. Ussyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

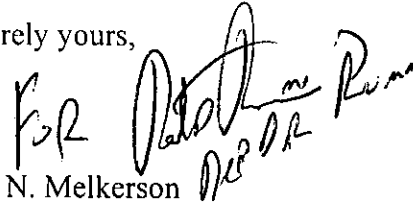
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



Exciton Technologies Inc.  
exsalt™ Wound Dressing

Premarket Notification 510(k)

### Indications for Use

510(k) Number (if known): K100580

OCT 12 2010

Device Name: exsalt™ Wound Dressing

Indications for Use:

The exsalt™ Wound Dressing is indicated for first aid to help minor cuts, scrapes, abrasion, lacerations and scalds.


Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100580

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